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Citric Acid Final Work Plan and Proposed Registration Review Final Decision Registration Review Case 4024

Docket Number EPA-HQ-OPP-2008-0855

Citric Acid Final Work Plan and Proposed Registration Review Final Decision Registration Review Case 4024

Approved By:

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Date:

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Final Work Plan and Proposed Registration Review Final Decision for Citric Acid, Case 4024

I. Introduction

This document is EPA's *Final Work Plan and Proposed Registration Review Final Decision* for the registration review of citric acid and is being issued pursuant to 40 CFR Sections 155.57 and 155.58. A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA. For additional information on citric acid, additional documents can be found in EPA's public docket (EPA-HQ-OPP-2008-0855) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States must generally be registered by EPA, based on scientific data showing that they will not cause unreasonable risks to human health (including occupational and non-occupational exposures) or the environment when used as directed on product labeling. The new registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the new registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/.

In 2006, the Agency implemented the Registration Review program pursuant to FIFRA Section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

Pursuant to 40 CFR Sec. 155.50, the Agency formally initiated registration review for citric acid with the following timeline:

- December 2008 – publication of a Preliminary Work Plan (PWP) in the docket for Citric Acid, and Salts (EPA-HQ-OPP-2008-0855). During the 90 day comment period that closed on March 17, 2009, the Agency received no comments from the public.
- June 2009 – Issuance of a Final Work Plan and Proposed Registration Review Final Decision stating that the most recent exposure and risk assessments still support the registration of pesticide products containing citric acid and meet the requirements of registration review under 40 CFR Sec. 155.50. This document also announced the removal of ammonium citrate (or ammonium salts) from the registration review case. This document will be issued for a 60-day public comment period.

This document is a combined Final Work Plan and Proposed Registration Review Final Decision. No comments were received on the Preliminary Work Plan (PWP), issued in December 2008. Given the lack of comments, the low toxicity of citric acid, and that no risk assessment was required, the Agency is combining the Final Work Plan

and Proposed Registration Review Final Decision Document for this case. The data and information evaluated to support citric acid, case 4024, as published in the PWP dated December 10, 2008, continue to support this pesticide registration as summarized herein. The status of these and other registration review cases is available on *http//www.epa.gov/oppsrrd1/registration review/ review*.

The Citric Acid case originally included both citric acid (PC Code 021801) and ammonium citrate [or ammonium salts (PC Code 021802)] and was referred to as the Citric Acid, and Salts case. However, ammonium citrate [or ammonium salts (PC Code 021802)] does not have any registered products (last product registration under PC Code 021802 was cancelled in 1989) nor is it being supported or addressed in this registration review. Citric acid (PC Code 021801) is the only active ingredient in the case with any registered pesticide products. Therefore, ammonium citrate (or ammonium salts) is being removed from case 4024 pursuant to 40 CFR 155.42(b)(5).

Citric acid is a food-contact and non-food contact antimicrobial pesticide used in many products for residential and public access premises (e.g. kitchen counter tops, bathroom shower stalls, toilets, utensils, kitchen cutting boards, diaper pails, changing tables, garbage cans, pet area, cafeterias and doctor's offices) and as a disinfectant fruit and vegetable wash, sanitizer, virucide, and germicide. It is also an inert ingredient in other pesticide products. In addition, citric acid is characterized by low toxicity, is biodegradable, and is found extensively in nature.

Currently, there are 27 registered products containing citric acid as an active ingredient. This Registration Review of citric acid addresses the citric acid component of the registered products. The other active ingredients will be addressed during their Registration Review. Citric acid is Generally Recognized As Safe (GRAS) (21 CFR 182.1033) by FDA for use in food as a general-purpose food additive and is also approved by the Joint FAO/WHO Expert Committee on Food Additives for use in foods without limitation. FDA regulation 21 CFR 178.1010 (b)(44) states that in addition to use on food-processing equipment and utensils, the solution of citric acid, disodium ethylenediaminetetraacetate, sodium lauryl sulfate, and monosodium phosphate may be used on dairy-processing equipment. FDA regulation 21 CFR 178.1010 (c)(38) states that the solution identified in paragraph (b)(44) of this section shall provide, when ready for use, at least 16,450 parts per million and not more than 32,900 parts per million of citric acid.

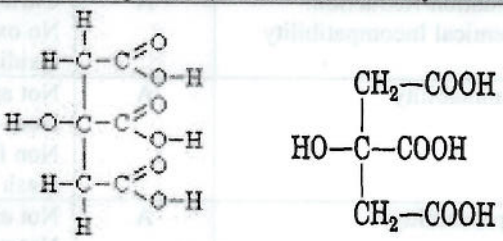
Citric acid is listed under 40 CFR 180.950 (e) as an exempt from a tolerance for purposes of food exposures. *§ 180.950 Tolerance exemptions for minimal risk active and inert ingredients* reads, "*Unless specifically excluded, residues resulting from the use of citric acid as either an inert or an active ingredient in a pesticide chemical formulation, including an antimicrobial pesticide chemical, are exempt from the requirement of a tolerance under FFDCA section 408, if such use is in accordance with good agricultural or manufacturing practices*." Citric acid is included on this list.

II. SCIENTIFIC ASSESSMENT

A. Chemical Identification

Table 1 provides information on the chemical identity of citric acid.

Table 1. Chemical Identity

Common Name	Citric acid
Chemical Name	Citric Acid Anhydrous citric acid 2-Hydroxy-1,2,3-propanetricarboxylic acid beta-Hydroxytricarballylic acid
PC Code	021801
CAS Registry Number	77-92-9
Registration Review Case No.	4024
Molecular Formula	$C_6H_8O_7$
Molecular Weight	192.1235 g/mol (Citric Acid Anhydrous)
Molecular Structure: HOC(CH2COOH)2COOH CH2COOH-C(OH)COOH-CH2COOH	 Citric Acid Anhydrous

B. Product Chemistry

Table 2 provides information on the physical and chemical properties of citric acid. All product chemistry data requirements have been fulfilled for the active ingredient citric acid; no additional data are needed at this time.

Table 2. Product Chemistry Data Summary for Citric Acid (TGAI >99.5%)

Guideline No.	Physical and Chemical Properties	Status[1]	Value
830.1550	Product identity and composition	A	Refer to Table 2
830.1600	Description of materials used to produce the product	A	CBI
830.1620	Description of production process	A	CBI
830.1650	Description of formulation process	A	CBI
830.1670	Discussion of formation of impurities	A	CBI
830.1700	Preliminary analysis	A	CBI
830.1750	Certified limits	A	CBI

Guideline No.	Physical and Chemical Properties	Status[1]	Value
830.1800	Enforcement analytical method	A	HPLC Ion Exclusion Chromatography
830.1900	Submittal of samples	N/A	
830.6302	Color	A	White Powder. Colorless, translucent crystal or white granular to fine crystalline powder at room temperature.
830.6303	Physical State	A	Granulated Powder Translucent crystal or white granular to fine crystalline powder at room temperature. Solid Crystals are monoclinic holohedra
830.6304	Odor	A	Strongly acid taste and is odorless
830.6313	Stability to sunlight, normal and elevated temperature, metals/metal ions	A	Stable under normal temperatures and pressures. Citric acid does not contain chromophores that absorb at wavelengths >290 nm and therefore is not expected to be susceptible to direct photolysis by sunlight.
830.6314	Oxidation/Reduction: Chemical Incompatibility	A	Citric acid is not an oxidizing or reducing agent. No oxidizing properties. Oxidizing or Reducing Action: Not applicable.
830.6315	Flammability	A	Not applicable. Does not contain any combustible liquids. Non flammable Flash Points: 100°C (212°F)
830.6316	Explodability	A	Not explodable Not potentially explosive Not applicable.
830.6317	Storage Stability	A	Stable. High humidity conditions and elevated temperatures should be avoided to prevent caking.
830.6319	Miscibility	N/A	Not applicable. Not meant for dilution with petroleum solvents.
830.6320	Corrosion Characteristic	A	Will corrode copper, zinc, aluminum and their alloys. Aqueous solutions of citric acid are mildly corrosive toward carbon steels. At elevated temperatures, 304 stainless steel is corroded by citric acid, but 316 stainless steel is resistant to corrosion. Many aluminum, copper, and nickel alloys are mildly corroded by citric acid. In general, glass and plastics such as fiber glass reinforced polyester, polyethylene, polypropylene, poly (vinyl chloride), and cross-linked poly(vinyl chloride) are not corroded by citric acid.
830.6321	Dielectric breakdown voltage	N/A	Not applicable. Not intended for use in or around electrical equipment.
830.7000	pH	A	The pH of citric acid is in the acidic range, from 0.8 for a 50 percent solution to 2.8 for a 0.1 percent solution. pH of 0.1 N solution equals 2.2 ~1.8 at 50 g/l and 25 °C

Guideline No.	Physical and Chemical Properties	Status[1]	Value
830.7050	UV/Visible absorption	N/A	Citric acid does not contain chromophores that absorb at wavelengths >290 nm.
830.7100	Viscosity	A	Not applicable. Citric acid is solid. 6.5 cP 50% aqueous solution at 25°C
830.7200	Melting Point	A	153°C but it decomposes before boiling
830.7220	Boiling point	A	Decomposition at 175°C
830.7300	Bulk Density	A	Density: 36.8 lbs/cubic feet for the loose material. Loose bulk density ranges from 54-57 lb/ft^3 1.665 g/cu cm at 20°C. Density: 1.665 g/ml
830.7300	Specific Gravity at 25°C	A	1.54 1.665 Specific gravity of a 10 percent solution is 1.035.
830.7370	Dissociation Constants in water Acidity (p*Ka*)	A	$K = 4 \times 10^{-4}$ at 25°C Citric acid dissociates in solution with a pK, of 4.761 Citric acid is a weak acid and has three carboxyl groups, hence three pK_a's. At 20°C pK1 = 3.14, pK2 = 4.77, and pK3 = 6.39
830.7550	Octanol/water partition coefficient	A	Not applicable Highly polar organic acid Technical chemical is polar
830.7840	Solubility in water (g/100ml)	A	62 g/100 ml at 25°C. Completely soluble in water. **Solubility in water:** 54.0% w/w at 10°C; 59.2% at 20°C; 64.3% at 30°C; 68.6% at 40°C; 70.9% at 50°C; 73.5% at 60°C; 76.2% at 70°C; 78.8% at 80 °C; 81.4% at 90°C; 84% at 100°C
830-xxxx	Solubility in organic solvents	A	Completely soluble in ethanol; but slightly soluble in chloroform, ethyl acetate, amyl alcohol, amyl acetate and diethyl ether Amyl acetate 4.2g/100g satd soln at 25°C Absolute diethyl ether 1.0 g/100g satd soln at 25°C Absolute ethyl alcohol 38.2 g/100g satd soln at 25°C
830.7950	Vapor pressure	A	1.7X10-8 mm Hg at 25°C (TOXNET) 0.0284 mm Hg at 25°C (Source: EPI Suite) 7.3 x 10- 7 Pa (25 °C) known to be nonvolatile
	Hazardous Polymerization		Will not occur
	Hazardous Decomposition Products		Decomposition: When heated above 175°C, citric acid decomposes to form aconitic acid, citraconic acid , itaconic acid, acetonedicarboxylic acid, carbon monoxide, irritating and toxic fumes and gases, carbon dioxide, and water.
	Autoignition Temperature		1850°F (1010°C)
Other Physical/Chemical Properties			
	Classification of a.i.		Carboxylic acid Organic acid

Guideline No.	Physical and Chemical Properties	Status[1]	Value
			Aliphatic acid Saturated Aliphatic Polycarboxylic Acids
	Pesticide Type		Antimicrobial
	Henry's Law Constant at 25°C		2.4083-015 atm-m3/mole (EPI Suite)
	Log Kow		–1.64 (EPI Suite) logPow = –1.72 at 20 °C
	Koc		Estimated Koc: 10 (EPI Suite)
	Log BCF		Log BCF = 0.50 (EPI suite) BCF= 3.162 (EPI suite)
	Photodegradation		Half-life = 18.273 Hrs (AOPWIN)
	Hydrolysis		No hydrolysis. Citric acid is not expected to undergo hydrolysis in the environment due to the lack of functional groups that hydrolyze under environmental conditions (TOXNET).
	Direct photolysis by sunlight		Not susceptible. Citric acid does not contain chromophores that absorb at wavelengths >290 nm and therefore is not expected to be susceptible to direct photolysis by sunlight (TOXNET).
	Assay		>99.5%
	Ready Biodegradability Prediction		Yes (EPI Suite)
	Modified Sturm Test		97% (CO2 evolution), Readily Biodegradable
	OECD 302B, Zahn-Wellens test		98% biodegraded in 48 hours
	TSCA 8(b) inventory		Citric acid
	Refractive Index		1.493-1.509 @20C

[1]A = Acceptable; N/A = Not applicable

C. Human Health Risk Assessment Status

A Reregistration Eligibility Decision (RED) document for citric acid was issued in 1992. At that time, all applicable toxicological, ecological and environmental fate requirements were waived. Based on the low toxicity of this active ingredient, the Agency reviewed the hazard and exposure databases for citric acid and currently anticipates that no additional toxicity and exposure data will be needed for registration review. In addition, the Agency does not anticipate that any occupational or residential handler assessments will be needed to ensure that the citric acid registration review case meets the standard for registration and safety factors in FIFRA and FFDCA, as amended by FQPA. For a detailed discussion of the human health risk assessment status, please refer to the *Revised Summary of Human Health Effects Data for the Citric Acid Registration Review Decision Document*, dated May 18, 2009. The citric acid, and salts RED can be located at: http://www.epa.gov/pesticides/reregistration/status.htm

1. Toxicology

The Agency has reviewed all toxicity studies submitted for citric acid and has determined that the toxicological database is sufficient and that additional toxicity studies for registration review are not needed. The toxicological database in the citric acid RED is currently comprised of published and unpublished studies either submitted to the Agency or obtained directly from published open literature.

The Food and Drug Administration (FDA) considers citric acid GRAS for use in foods under 21 CFR 582.1033. Citric acid is a normal part of the metabolism in living organisms as part of the Krebs or citric acid cycle (e.g. part of cellular respiration). The human body contains about 80 grams of citrate (mostly in bone). Citric acid is widely distributed in plants and animals and is normally present in food in substantial quantities. For example, one eight-ounce glass of orange juice provides about 2 grams of citric acid (USEPA, 1992).

a. Acute Toxicity

For acute toxicity, the acute oral LD_{50} for rats is 3 gm/kg which results in citric acid being ranked as toxicity category III. As a technical ingredient, citric acid is a severe eye irritant (toxicity category I) and causes moderate irritation to skin (toxicity category III).

b. Subchronic and Chronic Toxicity

Subchronic toxicity studies indicate that a 5 percent concentration of citric acid in the diet of rabbits for 150 days caused some effects on growth and survival, but no gross or histopathologic changes. An oral dose of 1,380 mg/kg/day for 112-120 days produced no evident abnormalities in dogs. Rats given 600 mg/kg/day orally for 90 days had no weight, blood, histopathological or reproductive effects. In a 1-year three-generation rat oncogenic/chronic toxicity feeding study, no adverse effects were noted on growth, reproduction, mortality, hematology, or metabolism at the highest dose level (800 mg/kg/day citric acid). Citric acid was not identified as carcinogenic. No subchronic or chronic inhalation toxicity studies were available. Citric acid was not found to be mutagenic in *in vivo* and *in vitro* tests such as host mediated assays in *Salmonella typhimurium*, chromosome aberration in rat bone marrow and rat dominant lethal assays (USEPA, 1992).

c. Endocrine Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) *"may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate."* Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific

bases for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupter Screening Program (EDSP) have been developed and vetted, citric acid may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

2. Dietary, Drinking Water, Residential and Occupational Exposure

a. Dietary and Drinking Water Exposure

A dietary risk assessment, including a drinking water assessment, is not needed for citric acid because exposures of concern are not anticipated. Citric acid is also listed under 40 CFR 180.950(e) as exempt from the requirement of a tolerance based on its minimal risk. The chemical is a normal part of the metabolism in living organisms as part of the Krebs or citric acid cycle (e.g. part of cellular respiration). The human body contains citrate, most of which is found in bone. Citric acid is widely distributed in plants and animals and is normally present in food in substantial quantities. It is also low in acute toxicity (tox category III). The FDA considers citric acid GRAS for use in foods under 21 CFR 582.1033. For a detailed discussion of the human health risk assessment status, please refer to the *Revised Summary of Human Health Effects Data for the Citric Acid Registration Review Decision Document*, dated May 18, 2009.

b. Residential and Occupational Exposure

Because the citric acid RED was completed prior to the advent of FQPA in 1996, a residential assessment was not conducted. Additionally, no other human health assessment was conducted, including an occupational assessment.

An occupational and/or residential exposure assessment is needed for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For citric acid, these toxicological criteria are not triggered. Therefore, the Agency does not need new occupational and residential risk assessments for registration review. EPA believes that because of the dilution of citric acid (many labels recommend dilutions as low as 1% active ingredient) in end-use registrations and the existing label requirements, the worker and/or resident is protected from any potential dermal or eye irritation effects identified in the toxicological studies of the technical active ingredient.

For a detailed discussion of the human health risk assessment status, please refer to the *Revised Summary of Human Health Effects Data for the Citric Acid Registration Review Decision Document*, dated May 18, 2009.

c. Aggregate and Cumulative Exposure

Citric acid is listed under 40 CFR 180.950(e) as exempt from a tolerance for purposes of food exposures. Also, FDA considers citric acid GRAS for use in foods under 21 CFR 182.1033. Risks associated with citric acid exposures are expected to be minimal based on limited evidence of any subchronic or chronic systemic effects through any route of exposure. EPA has not yet determined whether citric acid has a common mechanism with other compounds; consequently a cumulative assessment will not be performed at this time.

D. Environmental Fate and Ecological Effects Risk Assessment Status

1. Environmental Fate and Ecological Effects

Citric acid is found extensively in nature and is completely biodegradable. It is present in a number of plants, animal tissues, and bodily fluids. It is a food-grade substance generally recognized as safe, non-volatile and relatively inert to aqueous hydrolysis. It is a normal component of the human and animal diet, and is an integral part of normal metabolic cycles. Microorganisms rapidly degrade citric acid in soil and water. Therefore, the Agency does not need any environmental fate or ecological effects studies at this time based on citric acid's natural occurrence, common use as a food item, and the lack of significant toxicity and reported adverse effects information. For a detailed discussion of the environmental fate and ecological effects status, please refer to the *Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Citric Acid Registration Review Decision Document* dated November 24, 2008.

2. Endangered Species

As mentioned previously, citric acid has low toxicity. The 27 citric acid-containing products are registered for indoor pesticidal use. Citric acid is found extensively in nature and is completely biodegradable. Specifically, citric acid occurs in a number of plants, and animal tissues and fluids. It is a food-grade substance generally recognized as safe, is non-volatile and relatively inert to aqueous hydrolysis. It is a normal component in human and animal diet and is an integral part of normal metabolic cycles. Microorganisms rapidly degrade citric acid in soil and water.

Citric acid is not expected to contaminate ground water or soil and does not accumulate in the food chain. Because of the rapid degradation of citric acid into components that do not pose a risk to aquatic organisms, the Agency is not conducting a down-the-drain assessment.

Based on indoor use patterns for antimicrobial end-use products, low exposure levels, the chemical's natural occurrence in the environment and living organisms, common use as a food item, lack of reported adverse effects information, and very low/non-toxicity potential of citric acid, the Agency expects that the registered uses of citric acid will have "no effect" (NE) on endangered or threatened terrestrial or aquatic

species, or their designated critical habitats, as listed by the U.S. Fish and Wildlife Service (USFWS) and the National Oceanic and Atmospheric Administration (NOAA). For a detailed discussion of the status of the environmental and ecological risk assessments for citric acid, please refer to the *Summary of Product Chemistry, Environmental Fate and Ecotoxicity Data for the Citric Acid, and Salts Registration Review Decision Document,* dated November 24, 2008.

E. Incidents

Federal law requires registrants of pesticides to inform EPA about any harmful effects of their products. There are 105 human incidents and 75 pet incidents related to citric acid use that were found during a search of the OPP Incident Data System (IDS). All of the symptoms involved in human incidents were minimal with no residual disability involved. The reported symptoms included rash, blisters, shortness of breath, congestion, abdominal pain, cough, fatigue, runny nose, body aches, swollen eyes, and corneal abrasion when exposed via the inhalation, dermal and ocular routes. For pet exposures, the symptoms included hair loss, difficulty breathing, and rashes.

There were 74 incident cases reported to the California Pesticide Illness Surveillance Program between the years 1987 and 2006. Of these 74 incidents, only four are identified as being specific to citric acid exposure. Via inhalation exposure, citric acid caused shortness of breath, throat irritation, chest tightness, wheezing, coughing, headache, nausea, and vomiting. Through eye exposure, citric acid caused irritation.

There are no citric acid specific incidents in the Poison Control Center data.

F. Public Comments

Pursuant to 40 CFR Sec. 155.50, the Agency formally initiated registration review for citric acid on December 17, 2008 with the opening of a docket and the issuance of a PWP for public comment. The Agency received no comments concerning the Preliminary Work Plan for citric acid during the 90-day public comment period. The public will be invited to comment on the Proposed Registration Review Final Decision for 60 days following the issuance of this document.

G. Environmental Justice

EPA seeks to achieve environmental justice - the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income - in the development, implementation, and enforcement of environmental laws, regulations, and policies. At this time EPA does not believe that use of pesticide products containing citric acid will cause harm or a disproportionate impact on at-risk communities. In the Preliminary Work Plan dated December 10, 2008, the Agency sought comment on environmental justice issues regarding citric acid. As mentioned previously, no comments were received.

For additional information regarding environmental justice issues, please visit EPA's website at: http://www.epa.gov/compliance/environmentaljustice/index.html.

H. Water Quality

Citric acid is not identified as a cause of impairment for any water-bodies listed as impaired under section 303(d) of the Clean Water Act, based on information provided at: http://oaspub.epa.gov/tmdl/waters_list.impairments?p_impid=3. The Agency sought submission of water quality data for citric acid when the Preliminary Work Plan was issued for comment. The Agency did not receive any comments on water quality issues.

I. Trade Irritants

Through the registration review process, the Agency solicited information on trade irritants and, to the extent feasible, took steps toward facilitating irritant resolution. Growers and other stakeholders were asked to comment on any trade irritant issues resulting from lack of Maximum Residue Levels (MRLs) or disparities in key export markets, providing as much specificity as possible regarding the nature of the concern. In the case of citric acid, there are direct and indirect food uses. As a direct food additive (results in direct contact with food), citric acid is used as a fruit and vegetable wash. As an indirect food additive (results in indirect contact with food), citric acid is used in food preparation areas (e.g., utensils, countertops, cutting boards, and dishes). Citric acid is also listed under 40 CFR 180.950(e) as exempt from the requirement of a tolerance based on its minimal risk. FDA considers citric acid GRAS for use in foods under 21 CFR 582.1033. The Agency did not receive any comments regarding the existence of any trade irritant issues associated with citric acid.

III. REGISTRATION REVIEW PROPOSED FINAL DECISION

The Agency has determined that no additional data are required at this time to support the registration of citric acid. The Agency has considered citric acid in light of the standard for registration and safety factors in FIFRA and FFDCA as amended by FQPA. EPA has found that there are not likely to be any unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, or to non-target organisms, from the use of products containing citric acid when currently required label instructions are followed. The Agency has found that it is not necessary to conduct a new risk assessment for this case and is therefore issuing a proposed final decision pursuant to 40 CFR 155.53 (c)(2) and 40 CFR 155.58.

As per 40 CFR Sections 155.57 and 155.58, the Agency proposes that the standards for Registration Review have been met and that the registrations of the aforesaid citric acid products should be maintained.

IV. NEXT STEPS AND TIMELINE:

Pursuant to 40 CFR Section 155.58, this Proposed Registration Review Final Decision document is being entered into the citric acid docket (EPA-HQ-OPP-2008-0855). The Final Work Plan is also included in this document. A Federal Register Notice will announce the availability of the Proposed Registration Review Final Decision and allow a 60 day comment period. If there are no significant comments or additional information submitted to the docket during that period that lead the Agency to change its proposed decision, EPA will issue a final decision for citric acid Case 4024. The Agency anticipates the final decision will be issued in FY 2010.

V. GLOSSARY of TERMS & ABBREVIATIONS

ai	Active Ingredient
AR	Anticipated Residue
ASTM	American Society for Testing and Materials
AWPA	American Wood Preserver's Association
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GENEEC	Tier I Surface Water Computer Model
GRAS	Generally Recognized as Safe
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking submitted studies.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Ambient Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances

PAD	Population Adjusted Dose
PAIRA	Pure Active Ingredient Radiolabelled
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLN	Special Local Need (Registrations Under Section 24©) of FIFRA)
TGAI	Technical Grade Active Ingredient
TEP	Typical End-Use Product
USDA	United States Department of Agriculture
UF	Uncertainty Factor
WPS	Worker Protection Standard